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| LILLING, H. J. EXAMINER | |
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| ART UNIT | PAPER NUMBER |
| 1808 | 5 |

DATE MAILED:

04/07/94

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents.

Claims 29-42 have been renumbered to be 21-34. Claims 21-24 are subjected to a Double Patenting Rejection based on copending parent application which has been allowed drawn to the same claims.

A reference relevant to the examination of this application may soon become available. Ex parte prosecution is SUSPENDED FOR A PERIOD OF SIX MONTHS FROM THE DATE OF THIS LETTER. Upon expiration of the period of suspension, applicant should make an inquiry as to the status of the application.

SERIAL NUMBER 08/067,797

Herbert J. Lilling

H.J. LILLING
703-308-2034
APRIL 05, 1994
ART UNIT 1808

HERBERT J. LILLING
PATENT EXAMINER
GROUP 180 - ART UNIT 1808

Serial No. 08/067,797
Art Unit 1808

-2-

15. Receipt is acknowledged of the status letters filed October 06, 1994 and November 09, 1994.

16. Claims 28-42 have been renumbered to be claims 20-34.

5 Claim 20 has been cancelled.

17. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use
15 the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as enabling for the claimed microorganisms in accordance with the U.S. Rules of Deposits.

20 It is apparent that the additional strains are required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the
25 enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of these additional strains. See 37 C. F. R. 1.802.

Serial No. 08/067,797
Art Unit 1808

-3-

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

b) all restrictions imposed by the depositor on the availability to the public of the deposited

Serial No. 08/067,797
Art Unit 1808

-4-

material will be irrevocably removed upon the granting of a patent;

5 c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

10 d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

15 e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

20 In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

18. Claims 25-34 are rejected under 35 U.S.C. § 112, first paragraph as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make.

5 The following decisions which may be pertinent to the claimed language which may be extremely broad for the microorganism, see: In re Fisher, 168 USPQ 18, 24 (June 11 1970)

10 Such improvements, while unobvious from his teachings, are still within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. that paragraph requires that
15 the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.....In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with
20 the degree of unpredictability of the factors involved.

In view of the broad claimed language, the above statement:

25 It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art..
30

19. The reference to Fleno et al, U.S. 5,356,810 would be within the scope of broad claim 25. The patent claim is within
35 the scope of the instant claims 25-32. Thusly, this Examiner cannot allow the instant claims based on the current record.

20. 35 U.S.C. § 101 reads as follows:

40 "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Serial No. 08/067,797
Art Unit 1808

-6-


Claims 21-24 are rejected under 35 U.S.C. § 101 because they are the same as in allowed parent application, Serial Number 07/837,120.

5 21. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

10 A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED
15 STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

20 22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone
25 number is (703) 308-0196.

30 H. J. Lilling: HJL
(703) 308-2034
Art Unit 1808
January 23, 1995


HERBERT J. LILLING
PATENT EXAMINER
GROUP 180 - ART UNIT 1808